

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of:	:
Manne S. REDDY et al.	:
	:
Application No.: 10/601,844	: Group Art Unit: 1624
	:
Filed: June 23, 2004	: Examiner: P. V. Ward
	:
For: AMORPHOUS LEVOCETIRIZINE	:
DIHYDROCHLORIDE	:
_____	X

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**SUPPLEMENTAL REPLY BRIEF**

Sir:

This paper is submitted in response to the second Examiner's Answer, dated February 4, 2011, for the above-identified application. Submission of a reply is due by April 4, 2011. Accordingly, this paper is being timely filed.

Appellants believe that the only difference between the first and second Examiner's Answers is a change to the paragraph numbered (4) on page 2. Upon reviewing the file for the application, the undersigned discovered that the information that had been given about the status of amendments in the Appeal Brief submitted on May 20, 2008, on page 2 thereof, was incorrect. Therefore, a replacement for that page is appended hereto.

When page 2 of the Appeal Brief is replaced with the new page, Appellants believe that the record will be complete and a proper decision can be made. There do not appear to be any new arguments in the second Examiner's Answer, and Appellants therefore are not making any additional rebuttal arguments. As stated in their previous

submissions, the rejections of claims 1-18 under 35 U.S.C. §§ 112, second paragraph, 102, and 103 are legally and scientifically unsound, and their reversal is respectfully solicited.

If any matters remain to be resolved in connection with this submission, please contact the undersigned directly to arrange for an expedited resolution.

Respectfully submitted,

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claims are appended hereto, including prior amendments and with the canceled and withdrawn claims identified.

#### 4. Status of Amendments

An amendment was submitted after the Final Rejection, on July 20, 2007, but was not entered. Other amendments that were submitted during prosecution have been entered.

#### 5. Summary of the Claimed Subject Matter

Independent claims 1-3 are directed to amorphous levocetirizine dihydrochloride, a drug compound having antihistaminic activity. Claim 2 specifies that the compound is substantially free from crystalline forms of the drug, and claim 3 specifies a particular X-ray powder diffraction pattern for the compound.

Independent claim 4 is directed to a pharmaceutical composition containing amorphous levocetirizine dihydrochloride.

Independent claim 6 is directed to a composition containing solid levocetirizine dihydrochloride, wherein at least 80% by weight of said levocetirizine dihydrochloride is in an amorphous form.

The remaining claims are dependent from an independent claim, and add limitations thereto.

#### 6. Grounds of Rejection to be Reviewed on Appeal

- A. Whether claim 3 is indefinite for referring to a drawing figure.
- B. Whether claims 2 and 10 are indefinite for their inclusion of the modifying word "substantially."
- C. Whether claims 1-16 are anticipated by teachings from any of the cited documents Tang et al. (*J. China Pharm. Univ.*, 2002), Pflum et al. (*Organic Process Research and Development*, 2001), and Van de Venne et al. (U.S. Patent No. 6,489,329).
- D. Whether claims 17 and 18 are rendered obvious by teachings from Van de Venne et al. (U.S. Patent No. 6,489,329).